

Notice of FDA Warning regarding the use of vaginal mesh:

The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare.

The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

The FDA will provide updates on its Web page:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm>.

Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update



**American
Urological
Association**

Education and Research, Inc.

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1948 – 2009



Dr. Rodney Appell served as Professor of Urology and Gynecology and Chief, Division of Voiding Dysfunction and Female Urology, at Baylor College of Medicine and held a large private practice in Houston, Texas. He was a highly respected surgeon in female urology and an active member of the American Urological Association (AUA), serving on the Practice Guidelines Committee and the Special Women's Issues in Urology Committee.

At the time of his death, he was Chair of the expert Panel that developed the Stress Urinary Incontinence Clinical Guideline. Directing the Panel members through the painstaking and analytical challenge of systematically reviewing clinical studies so that appropriate practice recommendations could be made was an undertaking at which Dr. Appell excelled. In remembering him, the current guideline Chair, Roger R. Dmochowski, M.D., Professor, Dept of Urologic Surgery, Vanderbilt University, speaking for the Panel, remarked that "Rodney will be missed by us all. His vision of mentorship was the inspiration for a whole generation of residents and fellows. Those of us who knew him will treasure the memory of his unique insight and clinical expertise."

After receiving his medical degree from Jefferson Medical College, Dr. Appell completed his surgical residency at George Washington University Medical Center and residency in urology at Yale University. Since that time and until his death he achieved extensive accomplishments in his field through research, clinical practice, and education activities. Consistently included in the publication *The Best Doctors in America*, Dr. Appell published over 100 full papers or editorials in peer-reviewed journals, authored several book chapters, was invited to participate in more than 200 lectureships and symposia, and delivered over 800 educational talks and presentations both across the United States and around the world. He served on the editorial boards of many publications, including the AUA Journal of Urology. In February 2008, he was awarded the Lifetime Achievement Award by the Society for Urodynamics and Female Urology and was named Continence Care Champion by the National Association for Continence.

Dr. Appell's leadership and expertise will be missed by all who knew him. The Stress Urinary Incontinence Guidelines Panel dedicates this Clinical Guideline to his memory.

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Introduction

Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations studied.¹ A large meta-analysis reported an estimated prevalence for urinary incontinence of 30% in women aged 30 to 60 years, with approximately half of the cases attributed to SUI;² another study reported the prevalence of SUI was 5% to 30% in European women.³ Many women in the United States (U.S.) elect to have a surgical procedure for management of their SUI symptoms each year. The first Female Stress Urinary Incontinence Clinical Guidelines Panel reviewed literature available up to January 1994 and published its report in 1997.⁴ Since that time, a new body of literature has emerged on primarily novel surgical interventions for the treatment of SUI. For these reasons, the American Urological Association (AUA) has elected to update the initial report on the Surgical Management of Stress Urinary Incontinence. The literature search used in this analysis had a conclusion date of June 2005; it is recognized that this guideline will likely change in response to new information and further developments in the field.

In the 1997 guideline, the index patient was an otherwise healthy female patient with SUI without significant pelvic organ prolapse. It has become apparent since the prior guideline that many women with SUI also have pelvic organ prolapse and that these two issues may be addressed concurrently. Therefore, in constructing this guideline update, the index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and prolapse who elects to have treatment of her

SUI along with surgical correction of prolapse. The current Female Stress Urinary Incontinence Guideline Update Panel (the Panel) was selected by the Panel chair and approved by the Practice Guidelines Committee (PGC) of the AUA. The Panel members are representative of different medical specialties and geographic regions of the U.S. and are from both academic and private institutions.

This report describes an analysis of efficacy and safety outcomes for surgical procedures for use in treatment of SUI and provides a guideline based on review of these data and/or panel consensus. It also offers a discussion about the diagnostic evaluation of the index patient and recommendations for outcomes reporting and future research.

Definitions

Stress urinary incontinence is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions. There are two principle causes of this symptom – SUI and the rarer stress-induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure). The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies. For the purposes of this guideline, it is assumed that patients in the extracted studies had surgical management of SUI.

Urgency refers to a sudden, compelling desire to pass urine which is difficult to defer⁵ or a strong need to pass urine for fear of leakage.⁶ Urge urinary incontinence is defined as

involuntary leakage accompanied by or immediately preceded by urgency.⁵ Mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.

Index patient

The index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and pelvic organ prolapse who elects to have treatment of her SUI along with surgical correction of pelvic organ prolapse. Either index patient may be untreated or previously surgically-treated and may have urethral hypermobility and/or intrinsic sphincter deficiency. Urethral hypermobility was defined by the author; no uniform definition was used.

Methodology

This guideline included analysis of those relevant factors (perceived risks and outcomes of the interventions, patient preferences and relative priorities of the interventions given limited health care resources) used to choose among alternative treatment interventions.⁷ The peer-reviewed medical literature was meta-analyzed to estimate outcomes of treatment modalities, and Panel members themselves served as proxies for patients in considering preferences. The steps taken to develop this guideline, further detailed in Chapter 2, included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval and dissemination. The Panel did not review needle suspensions or anterior colporrhaphy in

developing this guideline update. Since development of the 1997 guideline, very limited new data has been published addressing these procedures, and there is a lack of current use or interest in them as well. Though these operations may still be performed in isolated circumstances by some surgeons, the Panel believes that they are largely of historical interest only and no longer considers these procedures contemporary treatments for SUI.

Problem Definition

This guideline update was based on the original AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997 using a similar methodology. The analysis was likewise limited to surgical treatments but included new procedures and those considered the most efficacious as determined by the previous analysis. Unlike the 1997 guideline, outcomes of surgical therapies for prolapse were also included.

Surgical efficacy was defined in three parts: 1) the resolution and lack of recurrence of SUI and urgency; 2) the resolution of prolapse and the lack of recurrence or new onset of prolapse; and 3) the incidence and severity of adverse events of these treatments. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on patient quality of life. The treatments included in the analysis were retropubic suspensions, slings, injection therapy and artificial sphincters; the analysis excluded those procedures not generally available in the U.S. or not expected to be approved at the time of publication. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. Procedures used to correct prolapse included hysterectomy in conjunction with or as a component of surgical treatment of SUI and site-specific repairs.

Literature Search and Data Extraction

A database was generated that included articles retrieved for the previous guideline and those resulting from a series of four MEDLINE® searches beginning in December 2002 and concluding in June 2005. The searches were limited to papers involving human subjects and published in the English language on or after 1990 which included the MeSH term “female.” The MeSH headings used were “urinary incontinence, stress,” “stress incontinence” and “urinary incontinence” in any field. A total of 7,111 citations and abstracts were reviewed for relevance by the panel chairs, of which 1,302 citations entered the extraction process. Panel members extracted data from the articles which were then entered into a Microsoft Access® (Microsoft, Redmond, WA) database. In person and via conference calls, the Panel collectively reviewed the extracted data. A total of 436 articles were suitable for inclusion in the meta-analysis; an additional 155 articles were deemed suitable only for their complications data due to an insufficient follow-up duration for the efficacy outcomes analysis.

Evidence Combination

To generate outcomes tables, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Combination can be performed in a variety of ways depending on the nature and quality of the evidence. For this guideline, the panel used the confidence profile method,^{8,9} which provides methods for meta-analyzing data from studies that are not randomized controlled trials (RCTs). Meta-analysis was performed using the Fast*Pro software to combine individual arms from controlled trials and clinical series where similar patients were similarly treated. Although a number of RCTs were found through the literature search, there were insufficient numbers on any one topic to warrant an independent meta-analysis of RCTs. The results of

certain trials are discussed where relevant. Frequently, published series used in a combined analysis showed very divergent results implying site-to-site variations, variability in patient populations, in the performance of the intervention, the skill of the surgeon or normal statistical variation. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

Patient Groups

While stratifying outcomes based on patient characteristics such as type of incontinence, previous treatment(s), presence of prolapse, prior pregnancy and severity of incontinence would be most instructive, in most cases the outcomes data were not fully or consistently identified by these criteria. Therefore, analysis was limited to two patient groups; one in which no patient received concomitant surgical treatment for prolapse (comparable to the previous guideline) and another in which some or all patients received concomitant treatment for prolapse. Very few published studies included all of the SUI patients receiving concomitant prolapse treatment, therefore, the analysis was based mainly on data from studies that included some patients with prolapse treatment. This did not permit a clear distinction to be made between these groups in the analysis. An attempt to stratify the outcomes of SUI surgical interventions by the presence of prolapse was thwarted by insufficient data since few published studies stratified results in this manner.

Efficacy Analysis

The efficacy outcomes analyzed included two levels of continence: cured/dry and cured/dry/improved; these are reported percentages and credible intervals (Bayesian confidence intervals [CIs]). Allocation to the previously mentioned categories was determined by author definition of continence. For the analysis of postoperative urgency, patients were divided into

three categories: without pre-existing urgency, with pre-existing urgency, and unknown or uncertain pre-existing urgency. Postoperative urgency categories included urge incontinence, urge symptoms and unspecified. Again, the results are reported as the percent of the relevant patient group having each outcome. Abbreviated tables summarizing the cured/dry and resolution or urge incontinence for the time interval of 12-23 months for patients with or without concurrent prolapse treatment are provided with this document (see Tables 1–3); for a complete set of data tables see Appendices A7-A16.

Complications

Complications were analyzed similarly to the efficacy outcomes. However, because of the wide variety of ways authors name and describe complications, the panel attempted to group complications together that represented the same or related outcomes. As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Appendix A-17 shows how the panel grouped outcomes. Certain complication outcomes such as pain and de novo urgency were tabulated as defined by the author, and no further analysis was performed based upon the limitations of data reporting. After grouping the complications for analysis, the grouped complications were then put into general categories for display and discussion. Outcomes tables were developed for each group of complications. Separate tables were again created for patients with and without prolapse treatment. The format of the tables is the same as the efficacy tables. An abbreviated table summarizing retention data for patients with or without concurrent prolapse treatment is provided with this document (see Table 4); for a complete set of data tables see Appendices A7 – A16.

Guideline Generation and Approvals

After the evidence was combined and outcome tables were produced, the Panel reviewed the results and identified anomalies, updated the outcomes tables based on the problems identified, and based on evidence from the outcome tables and expert opinion, the Panel drafted the treatment guideline. Based on 24 peer reviewer comments, the Panel revised the document. The guideline was submitted for approval to the PGC of the AUA and the Board of Directors for final approval.

As in the previous guideline, the present statements are graded with respect to the degree of flexibility in application. Although the terminology has changed slightly, the current three levels are essentially the same as in the previous guideline. A "standard" has the least flexibility as a treatment policy. A "recommendation" has significantly more flexibility, and an "option" is even more flexible. These terms are defined as follows:

1. **Standard:** A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. **Recommendation:** A guideline statement is a recommendation if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable, but not unanimous majority agrees on which intervention is preferred.
3. **Option:** A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

Dissemination

The guideline is published on the web site for the AUA and can be found at

<http://www.auanet.org>. A version of Chapter 1 will be published in the *Journal of Urology*.

Diagnostic Evaluation of the Index Patient

The purpose of diagnostic evaluation is three-fold: 1) to document and characterize SUI; 2) to assess differential diagnosis and comorbidities; and 3) to prognosticate and aid in the selection of treatment.

To confirm the diagnosis and characterize SUI

Stress urinary incontinence may be characterized by the following:

- demonstration of leakage with increasing abdominal pressure (see below)
- frequency of incontinence episodes (diagnosed by history, questionnaire, bladder diary)
- severity (the volume of urine leakage diagnosed by history, questionnaire, bladder diary, pad test)
- degree of bother (diagnosed by history, bladder diary, questionnaire)
- sphincter function (diagnosed by examination, Valsalva leak point pressure, urethral pressure profile)
- degree of urethral mobility (diagnosed by estimation at time of physical examination, cotton-swab test, or imaging)

On the basis of a focused history and physical examination with a comfortably full bladder, the diagnosis of SUI is fairly straightforward in the index patient. The *sine-qua-non* for a definitive diagnosis is for the examiner to witness involuntary urine loss from the urethral meatus

coincident with increased abdominal pressure (positive stress test) such as those occurring during coughing and straining; a standing position may facilitate the diagnosis. Once the increase in abdominal pressure has subsided, flow through the urethra should subside. Rarely, one may witness urine loss after increases in intra-abdominal pressure. In this scenario, one should suspect that the incontinence is, at least in part, due to an abnormal detrusor contraction (stress-induced detrusor overactivity).

To assess differential diagnosis and comorbidities

The differential diagnosis of stress incontinence includes detrusor overactivity, low bladder compliance, overflow incontinence, stress-induced detrusor overactivity, urethral diverticulum, urinary fistula and ectopic ureter. Overflow incontinence is a clinical diagnosis, whereas detrusor overactivity, low bladder compliance, and stress-induced detrusor overactivity are essentially urodynamic diagnoses while urethral diverticulum and urinary fistula can be sometimes be confirmed on the basis of history and exam but may in some instances require urinary tract imaging or other procedures for confirmation. Various imaging techniques for urethral diverticula may be used. Urinary fistula and ectopic ureter may be diagnosed by examination, cystoscopy and upper and lower urinary tract imaging.

Certain comorbidities relating to coexisting conditions might affect the outcome of treatment and influence surgical technique and the specifics of patient counseling. For example, a patient with mixed and stress incontinence who has a large post-void residual volume and impaired detrusor contractility might be counseled that her urge symptoms are more likely than usual to persist and that urinary retention is more likely. Further, the technique of surgery might be tailored such that a mid urethral, rather than bladder neck, sling is performed and it might be placed a bit looser than otherwise. These comorbidities include:

- urinary urgency and urge incontinence (diagnosed by history, questionnaire, bladder diary);
- anatomic features such as pelvic organ prolapse (diagnosed by history, exam); urethral mobility and other urethral abnormalities such as intrinsic stricture disease (diagnosed by cystoscopy, cotton-swab test, ultrasound);
- the number and location of ureteral orifices e.g. ectopic (diagnosed by cystoscopy); and/or
- the presence of detrusor overactivity, urethral obstruction, low bladder compliance and impaired or absent detrusor contractility (diagnosed by uroflow, postvoid residual volume determination, urodynamics).

To aid in prognosis and selection of treatment

There are few facts and many opinions about predicting the outcome of surgery based on the comorbidities described above, though few would disagree that operations for SUI should be confined to those who actually have demonstrable SUI, including occult SUI demonstrable only after reduction of pelvic organ prolapse. There is no standardized way to reduce a prolapse to unmask stress incontinence, and this patient falls outside the index patient identified by the panel. Nevertheless, an understanding of the specific comorbidities allows for individualized treatment planning, for informed consent and for the surgeon's estimate of a successful outcome and the potential occurrence of complications such as incomplete bladder emptying, persistent or de novo urgency/urge incontinence and recurrent sphincter incontinence. Urodynamic evaluation may be of assistance in elucidating complex presentations of incontinence.

Diagnostic Guidelines for the Index Patient

Amendments to 1997 Standards, Recommendations and Options are indicated (words that are in italics denote changes from the 1997 guideline document to improve clarity).

Standard: The evaluation of the index patient should include the following components:

- *Focused* history
- *Focused* physical examination
- Objective demonstration of SUI
- *Assessment of postvoid residual urine volume*
- Urinalysis, and culture if indicated

[Based on Panel consensus]

Recommendation: Elements of the history should include the following:

- Characterization of incontinence (stress, urge, etc.)
- Frequency, bother and severity of incontinence episodes
- Impact of symptoms on lifestyle
- Patient's expectations of treatment

[Based on Panel consensus]

Recommendation: Additional diagnostic studies can be performed to assess the integrity and function of the lower urinary tract.

- Pad testing and/or voiding diary
- Urodynamics

- Cystoscopy
- Imaging

[Based on Panel consensus]

Recommendation: Indications for further testing include the following:

- **An inability to make a definitive diagnosis based on symptoms and the initial evaluation**
- **Concomitant overactive bladder symptoms**
- **Prior lower urinary tract surgery, including failed anti-incontinence procedures**
- **Known or suspected neurogenic bladder**
- **Negative stress test**
- **Abnormal urinalysis such as unexplained hematuria or pyuria**
- **Excessive residual urine volume**
- **Grade III or greater pelvic organ prolapse**
- **Any evidence for dysfunctional voiding**

[Based on Panel consensus]

The need for further evaluation of any given patient depends on a number of other factors including the degree of certainty and comfort that the physician has about the diagnosis, the impact that further studies will have on diagnosis, treatment options and treatment risks and likely outcomes as well as the desire and willingness of the patient to undergo further studies.

Therapeutic Options

Nonsurgical Treatment

Management of SUI includes the option of nonsurgical therapies. The Panel did not review nonsurgical therapies because they are outside the scope of this report.

Surgical Treatment

The outcomes analyzed fell into two general categories: efficacy outcomes and complications. The results of the analysis are provided under each treatment below. For a more detailed discussion of the outcomes, see Chapter 3. Comparative results of the meta-analysis of efficacy and complications are shown in the tables and graphs in Chapter 3.

Outcomes Analysis

Efficacy

The primary efficacy outcome was the resolution of stress incontinence as measured two ways—patients who were completely dry (cured/dry) or patients who showed improvement (cured/dry/improved). The cured/dry/improved measure may include patients who were completely dry. Secondary efficacy outcomes dealt with changes in urgency as described in the methodology section above. Data were accepted as reported except when described in terms that conflicted with the definition in the methodology. For example, if a study reported any patients with minimal persistent incontinence as cured, these data were included only in the cured/dry/improved category.

Outcomes were analyzed separately based on whether the continence evaluation was subjective or objective; only results that were clearly based on subjective or objective criteria

were included in their respective analyses. An additional category was created (defined as “any” method of evaluation) to include all studies irrespective of the method of assessment used. For studies reporting both subjective and objective results, the subjective results for the study were included in the “any” category.

Outcomes also were analyzed separately according to the postsurgical interval of the final assessment of continence, with a minimum period of follow-up of 12 months. Three intervals were analyzed: 12 to 23 months, 24 to 47 months and greater than 48 months. If a study reported data at multiple times during one of these intervals, the time point closest to 18 months, 36 months and 60 months were used for the three time ranges, respectively.

Complications

In order to facilitate the analysis of complications for the various SUI surgical procedures and because of the lack of standardized complications nomenclature in the literature the Panel grouped the reported complications into the following classes:

- Urinary retention • Perioperative genitourinary • Delayed genitourinary
- Gastrointestinal • Vascular • Neurological
- Infectious • General medical • Death

Details of these groups are described in Chapter 3. Appendix A-17 lists the specific complications that were included in each of the above classes. Subjective complications (pain, sexual dysfunction, and voiding dysfunction) were also included as a separate category. Important complications for specific treatments are discussed below under the relevant treatment.

Surgical Treatments Analyzed - Descriptions and Outcomes

The surgical treatments analyzed fell into four categories: retropubic suspensions, slings, injectable agents and artificial urinary sphincters (AUS). Within each class, modifications of these treatments were analyzed where appropriate. For some categories, only minimal data were available. As noted in the methods section, definitions of cured, dry and improved were those of the authors.

In this section, brief descriptive results are provided for outcomes. The complete results are provided in Chapter 3 and Appendices A7-A16.

Retropubic Suspensions

Although the techniques for performing retropubic suspensions were essentially unchanged since the 1997 Guideline, the Panel elected to determine if there were any new studies since that analysis that would result in significantly different outcomes. Data from three categories of retropubic suspensions were analyzed: 1) open suspensions regardless of type (including Burch suspensions); 2) open Burch suspensions alone; and 3) laparoscopic suspensions.

The Panel's meta-analysis estimated cured/dry rates at 12 to 23 months based on 1,085 patients for open suspensions with no concomitant prolapse treatment to be 82% (CI: 74%-87%) while cured/dry rates for laparoscopic suspensions were 69% (368 patients; CI: 52%-84%) (Table 1). At 24 to 47 months, the cured/dry rates were similar among all procedures, ranging from 74% to 76%. At 48 months or longer, cured/dry rates for all open procedures were 73%. No data were available for laparoscopic procedures. These rates are similar to those reported for retropubic suspensions in the previous Guideline, in which estimated cured/dry rates were 84% at all time points.⁴

The meta-analysis estimate of postoperative urge incontinence was 14% from data from 186 patients (CI: 6%-25%) with pre-existing urge incontinence when treated with open retropubic suspensions, while de novo urge incontinence and “unspecified” urge incontinence was estimated in 8% (713 patients; CI: 5%-12%) and 41% of patients (305 patients; CI: 30%-54%), respectively (Table 3). Of patients undergoing laparoscopic retropubic suspensions, the meta-analytic results indicate that an estimated 5% of patients (CI: 1%-14%) will experience de novo urge incontinence and approximately 6% (CI: 1%-14%) will have “unspecified” urge incontinence. There were few data available for laparoscopic retropubic suspensions or for longer term outcomes of open retropubic suspensions (for longer term outcomes on urge incontinence, see Chapter 3). Based on 1,154 patients in 18 studies, retention could occur in 3% to 4% of patients (Table 4). The most common complications and estimated rates of occurrence for open retropubic suspensions determined in the meta-analysis (see Chapter 3) were febrile complications (8%), urinary tract infection (13%), bladder injury (4%) and voiding dysfunction (9%). Laparoscopic suspensions appeared to have a lower overall risk of febrile complications (0% reported) and urinary tract infection (2%), although these estimates were based on limited data. Ureteral injury was estimated to occur in 4-11% of patients receiving laparoscopic retropubic suspensions (see later discussion in Chapter 3), but only 1% of patients receiving open suspensions. Again, these estimates were based on a very small number of patients.

For patients with concomitant prolapse treatment, the estimated cured/dry rates for open retropubic suspensions, Burch suspensions and laparoscopic suspensions were all 88% at 12 to 23 months and 83% to 85% at 24 to 47 months (Table 2). The cured/dry rate was estimated to be 67% (1,072 patients; CI: 56%-76%) for all open retropubic suspensions at 48 months or longer, and data were insufficient for an approximation of efficacy for laparoscopic therapy at 48 months

or longer. The postoperative urge incontinence rate was based on 143 patients with pre-existing urge incontinence who were treated with open retropubic suspensions with concurrent prolapse repair; the rate of occurrence was approximately 22% (CI: 4%-56%). Further, the analysis estimates 14% of patients (457 patients; CI: 8%-21%) may experience de novo urge incontinence and 13% of patients (256 patients; CI: 7%-22%) may report “unspecified” urge incontinence (Table 3). By comparison, the results estimate that 11% of patients treated with laparoscopic suspensions will have de novo urge incontinence (344 patients; CI: 6%-17%); data were unavailable or insufficient for the other urge incontinent outcomes with laparoscopic retropubic suspensions (for longer term outcomes on urge incontinence, see Chapter 3). Retention was estimated in 1% to 2% of patients (Table 4).

Slings

Autologous Fascial Slings

Efficacy data were available for a variety of types of autologous fascial slings, including suprapubic slings with bone anchors, autologous vaginal wall slings with or without bone anchors and the general category of autologous fascial slings without bone anchors (detailed outcomes for the different types of autologous fascial slings are provided in Chapter 3).

Most of the available studies described patients treated with autologous slings without bone anchors. For patients without concurrent prolapse treatment, the estimated cured/dry rates ranged between 90% at 12 to 23 months and 82% at 48 months or longer (Table 1). The Panel’s meta-analysis estimated rates of postsurgical urge incontinence were 33% in patients with pre-existing urge incontinence and de novo urge incontinence in 9% of patients without pre-existing urge incontinence (Table 3). The estimated rate of retention was 8% (Table 4). Complications estimates for autologous fascial slings without bone anchors were generally infrequent and

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included urinary tract infection (11%), bladder injury (4%) and wound complications (8%). There were also a few studies published between 2001 and 2003 reporting data on a small number of patients who received autologous fascial vaginal wall slings with or without bone anchors. Complete data are provided in Chapter 3.

For patients treated with autologous slings without bone anchors and a concurrent prolapse treatment, cured/dry rates ranged from 85% to 92%, although these estimates were based on a very small number of patients (Table 2). Based on the results of the meta-analysis, approximately 10% of patients could experience de novo urge incontinence, and an estimated 5% of patients will be subject to retention (Table 3).

Cadaveric Slings

Cadaveric slings came into wide use following a report by Handa et al.,¹⁰ and other authors have since reported favorable results using this procedure.^{11, 12} However, the long-term durability of these procedures has been questioned,^{13, 14} with reports of graft failure^{15, 16} and declining success rates over time^{17, 18} (for a more complete discussion on the use of cadaveric slings, see Chapter 3). The use of these materials has dramatically declined over time as a result of these concerns, thus severely limiting data available for analysis.

Based on the limited data available for analysis, the estimated cured/dry rate for patients undergoing cadaveric slings without bone anchors and no concomitant prolapse treatment was 74% at 12 to 23 months and 80% at 24 to 47 months (Table 1). There were no data for longer term efficacy (48 months or longer) for cadaveric slings, and few studies reported data on retention, urge incontinence or complications.

For patients with concomitant prolapse treatment, the Panel's meta-analysis estimates of cure/dry rates were 82% (234 patients CI: 77%-86%) at 12 to 23 months using a cadaveric sling

with bone anchors, whereas the rate was 58% based on patients from three studies totaling 133 patients (CI: 36%-78%) where bone anchors were not utilized (Table 2). Despite the fact that these confidence intervals barely overlap, the consensus of the Panel is that these represent statistical aberrations inherent in evidence combination and are likely not representative of a true difference in outcomes. There were no data for bone-anchored slings beyond two years. At 24 to 47 months, for patients undergoing a cadaveric sling procedure without bone anchors in addition to prolapse treatment, the cured/dry rate was 64%, and at > 48 months based on 13 patients, only an estimated 31% receiving a cadaveric sling without bone anchor will be cured/dry.

Little is known about the graft-host relationship and possible mechanisms of graft degradation for cadaveric materials. In addition, processing and storage of these materials is variable, which could account for the disparity of results as reflected by the wide CIs in our analysis. There were insufficient data to assess the long-term efficacy of these procedures, with very few studies reporting results at 48 months or longer. Furthermore, the risks of disease transmission with these materials remain unknown. Traces of genetic material have been isolated from commercially available cadaveric sling materials¹⁹ although there have been no reports of disease transmission related to cadaveric grafts in the urologic literature.

There were few complications reported in the literature for procedures using cadaveric sling materials. Vaginal extrusion was reported in one study,²⁰ but erosion of cadaveric materials into the urinary tract was not identified in this meta-analysis. Other reported complications were similar to other procedures for the surgical correction of SUI. When these materials have been used with concomitant prolapse repair, complications such as infection and graft extrusion have been reported.²¹